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10/031,767	01/23/2002	Gary S. Jacob	3229/1/PCT	8501

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 04/08/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/031,767

Applicant(s)
Jacob et al.

Examiner
Michele Flood

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 23, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Art Unit: 1654

DETAILED ACTION

Claim *Rejections* - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-13 are rejected under 35 U.S.C. 112, second paragraph as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 recites the limitation "The method of treating a patient affected with a glycolipid storage disease" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "The" with A.

An obvious typographical error appears in Claim 7, line 2. Applicant may overcome the rejection by replacing "in" with is.

Claims 3-5 and 11-13, recite the abbreviation "DNJ". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

Each of Claims 2-9 and Claims 11-13 recites the phrase "in which", which places the claims in poor grammatical form. Applicant may overcome the rejection by replacing "in which" with wherein.

Art Unit: 1654

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by

Aerts et al. (WO 98/02161).

Applicant claims a method of treating a patient affected with a glycolipid storage disease comprising administering to the patient both a N-alkyl derivative of deoxynojirimycin having from about two to twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme in an amount effective for alleviating or inhibiting the glycolipid storage disease. Applicant further claims the method of wherein the N-alkyl derivative of deoxynojirimycin contains four to six carbon atoms in the alkyl chain; and wherein the N-alkyl derivative of deoxynojirimycin is N-butyl-DNJ. Applicant further claims a method wherein the glycolipid storage disease is Gaucher's disease. Applicant further claims a combination drug composition comprising a N-alkyl derivative of deoxynojirimycin having from about two to twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme in a pharmaceutically acceptable diluent or carrier.

Aerts teaches a method of treating a patient affected with a glycolipid storage disease, such as Gaucher's disease, comprising the administration of dose amounts of a composition of

Art Unit: 1654

deoxynojirimycin derivatives and their salts containing 3 to 8 carbons or 3 to 6 carbons in combination with an effective amount of glucocerebrosidase. See Claim 16 and TABLE 3 on page 30, wherein Aerts demonstrates the activity of various glucocerebrosidases and glycosylceramidase in combination with N-alkyl derivatives of deoxynojirimycin, including N-butyl-deoxynojirimycin. Aerts further teaches the claimed combination drug composition.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt et al. (US Patent 5,798,366) in view of Shorr et al. (A).

Applicant claims a method of treating a patient affected with a glycolipid storage disease comprising administering to the patient both a N-alkyl derivative of deoxynojirimycin having from about two to about twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme in an amount for alleviating or inhibiting glycolipid storage disease. Applicant further claims a method wherein the N-alkyl derivative of deoxynojirimycin contains four to six carbon atoms in the alkyl chain; wherein the N-alkyl derivative of deoxynojirimycin is N-butyl-DNJ. Applicant further

Art Unit: 1654

claims a method wherein the glycolipid storage disease is Gaucher's disease. Applicant further claims a method wherein the N-alkyl derivative of deoxynojirimycin is administered in a dose of from about 0.1 to about 1000 mg and the glucocerebrosidase is administered in a dose of about 7.5 to about 30U per kilogram of weight of the patient in a pharmaceutically acceptable diluent or carrier.

Platt teaches a method of treating the glycolipid storage diseases, Gaucher's disease, Fabry disease, Tay-Sachs disease, Sandhoff, GM1 gangliosidosis and fucosidosis, comprising the administration of N-alkyl derivatives of deoxynojirimycin having from 2 to about 8 carbon atoms, such as N-butyl-DNJ, in dose amounts of 0.01 to 1000 mg. Platt does not treat a method of treating a glycolipid storage disease comprising both the administration of deoxynojirimycin and a glucocerebrosidase enzyme. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treatment taught by Platt by adding a glucocerebrosidase enzyme because Shorr teaches a method of treating Gaucher's disease by the administration of a composition comprising conjugates containing glucocerebrosidase and polyethylene glycol in dose amounts from about 0.1 IU/kg to about 200⁺ IU/kg, and preferably 2-6 IU/kg, in Column 5, lines 3-29. One of ordinary skill in the art would have been motivated and had a reasonable expectation of success to provide a method for the treatment of glycolipid storage diseases comprising the administration of both of the instantly claimed ingredients because at the time the invention was made both deoxynojirimycin and glucocerebrosidase were known as effective drugs that were useful in the treatment of glycolipid

Art Unit: 1654

diseases, such as Gaucher's disease. Thus, the claimed method and claimed product are no more than the additive effect of two well known ingredients used in the art for the same purpose.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 4, 5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt et al. (US Patent 5,798,366), in view of Legler et al. (U), and further in view of Shorr et al. (A).

Applicant claims a method of treating a patient affected with a glycolipid storage disease comprising administering to the patient both a N-alkyl derivative of deoxynojirimycin having from about two to about twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme in an amount for alleviating or inhibiting glycolipid storage disease. Applicant further claims a method wherein the N-alkyl derivative of deoxynojirimycin is N-nonyl-DNJ or N-decyl-DNJ. Applicant further claims a method wherein the glycolipid storage disease is Gaucher's disease. Applicant further claims a combination drug composition comprising N-nonyl-DNJ or N-decyl-DNJ, and a glucocerebrosidase enzyme in a pharmaceutically acceptable diluent or carrier.

Platt teaches a method of treating the glycolipid storage diseases, Gaucher's disease, Fabry disease, Tay-Sachs disease, Sandhoff, GM1 gangliosidosis and fucosidosis, comprising the administration of N-alkyl derivatives of deoxynojirimycin having from 2 to about 8 carbon atoms, such as N-butyl-DNJ, in dose amounts of 0.01 to 1000 mg. Platt does not teach a method of

Art Unit: 1654

treating glycolipid storage diseases with either N-nonyl-deoxynojirimycin (N-nonyl-DNJ) or N-decyl deoxynojirmicycin (N-decyl-DNJ). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the N-alkyl derivatives of deoxynojirimycin taught by Platt with either N-nonyl-DNJ or N-decyl-DNJ because Legler teaches the inhibition of glucosylceramidase by long chain N-alkyl derivatives of deoxynojirimycin, including N-nonyl-deoxynojirmicycin and N-decyl-deoxynojirmicycin. One of ordinary skill in the art at the time the invention was made would have been motivated and one would have had a reasonable expectation of success to substitute one for the other because Platt and Legler teach that the N-alkyl-deoxynojirimycin derivatives demonstrate the same functional effect. Neither Platt nor Legler teach a method of treating glycolipid storage diseases comprising both the administration of deoxynojirimycin and a glucocerebrosidase enzyme. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combined teachings of Platt and Legler by adding a glucocerebrosidase enzyme to provide the claimed method of treatment and claimed combination drug comprising N-nonyl-DNJ or N-decyl-DNJ, and a glucocerebrosidase enzyme because Shorr teaches a method of treating Gaucher's disease by the administration of a composition comprising conjugates containing glucocerebrosidase and polyethylene glycol in dose amounts from about 0.1 IU/kg to about 200⁺ IU/kg, and preferably 2-6 IU/kg, in Column 5, lines 3-29. One of ordinary skill in the art would have been motivated and had a reasonable expectation of success to provide a method for the treatment of glycolipid storage diseases comprising the administration of both of the instantly

Art Unit: 1654

claimed ingredients because at the time the invention was made because both N-alkyl derivatives of deoxynojirimycin, such as the instantly claimed nonyl-DNJ or N-decyl-DNJ, and a glucocerebrosidase enzyme were known as effective drugs that were useful in the treatment of glycolipid diseases, namely Gaucher's disease.

Thus, the claimed method is no more than the combination of well known methods employing well known drugs each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Art Unit: 1654

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 of copending Application No. 10/054,802. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1654

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 10-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 10, 11, 14, 15, 25-27, 33-35 and 38 of copending Application No. 10/042,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are merely obvious variants of each other.

To the extent that they are enabled by the disclosure, the claims of the instant application are drawn to a method of treating a patient affected with a glycolipid storage disease comprising administering to a patient a combination of a N-alkyl derivative of deoxynojirimycin having about two to about twenty carbon atoms in the alkyl chain and a glucocerebrosidase enzyme in a combined amount therapeutically effective for alleviating or inhibiting the glycolipid storage

Art Unit: 1654

disease. Herein, Claims 6-8 limit the treatment to Gaucher's disease. The claims of copending Application No. 10/042,527 are directed to a method of treating a glycolipid storage-related disorder comprising administering a therapeutically effective amount of an inhibitor of glycolipid synthesis in combination with an agent capable of increasing the rate of glycolipid degradation; wherein the agent capable of increasing the rate of glycolipid synthesis is an imido sugar selected from the group consisting of N-butyldeoxynojirimycin (NB-DNJ) or N-butyl-DNJ, N-butyldeoxygalactonojirimycin (NB-DGN), and N-nonyldeoxynojirimycin (NN-DNJ) or N-nonyl-DNJ; wherein the glycolipid storage-related disorders includes Gaucher's disease; wherein the agent capable of increasing the rate of glycolipid degradation is an enzyme involved in glycolipid degradation includes glucocerebrosidase; and, wherein the inhibitor of glycolipid synthesis and the agent capable of increasing the rate of glycolipid degradation are given simultaneously or in combination.

Thus, the conflicting claims, although not identical, are not patentably distinct from each other because the claims are merely obvious variants of each other for methods of treating the same disease condition comprising administering the identical or at least very similar ingredients.

This is a provisional obviousness-type double patenting rejection.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

April 3, 2003

Michele C. Flood
MICHELE FLOOD
PATENT EXAMINER